MATERIAL SAFETY DATA SHEET

Product Name: Ceftriaxone for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Ceftriaxone for Injection

Synonyms
(6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo-3-yl-triazin-3-yl)thio][methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 72-(Z)-(0-methyloxime), disodium salt, sesquaterhydrate.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Ceftriaxone Sodium

Chemical Formula
C18H16N8Na2O7S3•● 3.5H2O

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Sodium</td>
<td>100</td>
<td>74578-69-1</td>
<td>XI0368800</td>
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</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Ceftriaxone for Injection is a powder for reconstitution containing ceftriaxone sodium, a cephalosporin antibacterial agent used to treat infections due to susceptible organisms. No adverse effects are anticipated from normal handling of the intact container. In the workplace, the powdered ceftriaxine sodium may produce skin, eye, or respiratory irritation and may induce an allergic response. The reconstituted product is not anticipated to be irritating. Persons known to be allergic to penicillins or other cephalosporins should take precautions when handling this material. Following an accidental over-exposure, possible target organs may include the gastrointestinal system, liver, kidneys, blood, and skin.

Occupational Exposure Potential
Minimal occupational exposure is anticipated from normal handling of the intact container. Avoid liquid aerosol generation and inadvertent skin contact.

Signs and Symptoms
No signs or symptoms of exposure are anticipated from normal handling of the intact container. Based on clinical use of this product in patients, following an accidental occupational exposure, possible adverse effects may include gastrointestinal upset (nausea, vomiting, stomach cramps, loss of appetite), headache, dizziness, elevated liver enzymes, elevated kidney enzyme levels, and altered hematological parameters (anemia, neutropenia, thrombocytopenia). Persons
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allergic to penicillins or other cephalosporin antibiotics may experience allergic reactions including fever, rash, itching, difficulty breathing, or anaphylaxis.

Medical Conditions Aggravated by Exposure: Pre-existing allergy to ceftriaxone sodium, penicillins, or other cephalosporin antibiotics. Pre-existing gastrointestinal system, liver, kidney, skin, or hematological ailments.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this product. However, many organic powders will combust at high temperatures.

Fire & Explosion Hazard
None anticipated for this product. Avoid the creation of dusty environments.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special requirements are needed for single units or packages. For larger amounts, self-contained breathing apparatus and protective equipment and clothing are recommended to minimize contact with respiratory tract, skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
If a container breaks, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations. If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special control measures are required during the normal use of this product.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary
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container label, or the product insert.

Special Precautions No special precaution required for hazard control. However, persons with known allergies to penicillins or other cephalosporins should consult a health or safety professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
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</thead>
<tbody>
<tr>
<td>Ceftriaxone Sodium</td>
<td>Not Applicable</td>
<td>mg/m3 ppm µg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A N/A N/A</td>
</tr>
</tbody>
</table>

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection
If contact with unprotected skin is possible, the use of gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to many chemical agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination.

Eye protection
Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls
Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State Solid
Color White to yellowish (light yellow to amber)
Odor Practically odorless
Odor Threshold: NA
pH: 6.7 for a 1% aqueous solution
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
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Solubility: Readily soluble in water, sparingly soluble in methanol and very slightly soluble in ethanol

Partition coefficient: n-octanol/water: NA

Auto-ignition temperature: NA

Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined.

Conditions to avoid Not determined.

Incompatibilities Not determined.

Hazardous decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), sodium oxides (Na2O), and sulfur oxides (SOx).

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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<tbody>
<tr>
<td>Ceftriaxone Sodium Hydrate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;10,000</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
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<td></td>
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<tr>
<td>Ceftriaxone Sodium Hydrate</td>
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<td>1900</td>
<td>mg/kg</td>
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<td></td>
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<td>mg/kg</td>
<td>Mouse</td>
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<td></td>
<td></td>
<td></td>
<td>&gt;3000</td>
<td>mg/kg</td>
<td>Dog</td>
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</table>

Aspiration Hazard None anticipated from normal handling of intact containers.

Dermal Irritation/Corrosion None anticipated from normal handling of intact containers.

Ocular Irritation/Corrosion None anticipated from normal handling of intact containers. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization None anticipated from normal handling of intact containers. As a class, cephalosporin antibiotics are sensitizers in studies in animals. Allergic reactions have been reported during the clinical use of this product.

Reproductive Effects Ceftriaxone produced no impairment of fertility when given intravenously to rats at daily dosages up to 586 mg/kg/day, about 20 times the recommended clinical dose of 2 gm/day. Reproductive studies in mice and rats at doses up to 20 times the usual human dose have shown no evidence of embryotoxicity,
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fetotoxicity or teratogenicity. In primates, no embryotoxicity or teratogenicity was noted at a dose about three times the human dose. In rats, in the Segment I (fertility and general reproduction) and Segment III (perinatal and postnatal) studies using intravenous ceftriaxone at doses of 586 mg/kg/day or less, no adverse effects were noted on various reproductive parameters during gestation and lactation, including postnatal growth, functional behavior and reproductive ability of the offspring.

Mutagenicity

The mutagenic potential of ceftriaxone was evaluated in the Ames test, a micronucleus test, and an in vitro test for chromosomal aberrations in human lymphocytes. Ceftriaxone showed no potential for mutagenic activity in these studies.

Carcinogenicity

Carcinogenicity studies with ceftriaxone in animals have not been conducted.

Target Organ Effects

Based on clinical use, possible target organs include the gastrointestinal system, liver, kidneys, blood, and skin.

12. ECOLOGICAL INFORMATION

| Aquatic Toxicity | Not determined for product. |
| Persistence/Biodegradability | Not determined for product. |
| Bioaccumulation | Not determined for product. |
| Mobility in Soil | Not determined for product. |

13. DISPOSAL CONSIDERATIONS

| Waste Disposal | All waste materials must be properly characterized. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements. |
| Container Handling and Disposal | Dispose of container and unused contents in accordance with federal, state and local regulations. |

14. TRANSPORTATION INFORMATION

| ADR/ADG/DOT STATUS: | Not regulated |
| IMDG STATUS: | Not regulated |
| ICAO/IATA STATUS: | Not regulated |
| Transport Comments: | None |

15. REGULATORY INFORMATION
# Product Name: Ceftriaxone for Injection

## USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
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<tbody>
<tr>
<td>Ceftriaxone Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
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</table>

**RCRA Status**: Not Listed  
**U.S. OSHA Classification**: Possible Sensitizer  
**Classification**: Target Organ Toxin

**GHS Classification**: *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

- **Hazard Class**: Not Applicable  
- **Hazard Category**: Not Applicable  
- **Signal Word**: Not Applicable  
- **Symbol**: Not Applicable  
- **Prevention**: P260 - Do not breathe dust/fume/gas/mist/vapors/spray.  
- **Hazard Statement**: Not Applicable  
- **Response**: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.

**EU Classification**: *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Ceftriaxone Sodium.

- **Classification(s)**: Not Applicable  
- **Symbol**: Not Applicable  
- **Indication of Danger**: Not Applicable  
- **Risk Phrases**: Not Applicable  
16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/17/2012
Obsolete Date: 10/24/2011

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